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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,371	12/10/2001	Ian R. Reid	HO-P02194US0	6234
26271	7590	03/24/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/016,371	<b>Applicant(s)</b> REID, IAN R.	
	<b>Examiner</b> Shaojia A Jiang	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9,11-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,11-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/10/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on December 16, 2003 wherein claims 1-4, 6-9, 11-15, and 17-21 have been amended; claim 22 is newly submitted; Claims 5, 10 and 16 are cancelled.

Currently, claims 1-4, 6-9, 11-15, and 17-22 are pending in this application.

Claims 1-4, 6-9, 11-15, and 17-22 as amended now are examined on the merits herein.

The following is new rejection(s) necessitated by Applicant's amendment filed on December 16, 2003, wherein the limitations in the new amended claims have been changed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-9, 12-15, and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "greater than 800 mg elemental calcium per day" which read literally on any amounts greater than 800 mg, without upper limit, and outside the original claimed range about 10mg to 1g. Most importantly, the original specification merely discloses administering 1g of calcium (two tablet each containing 400 mg of calcium) in Example 2 [0066], 910mg at Table 1, and the original specification fails to disclose administering greater than 1 g of calcium. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), regarding a corresponding new claim limitation with no upper limit. See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). Moreover, given the fact that any amounts greater than 800 mg to be administered to a postmenopausal woman might cause serious toxicity.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-9, 11-15, and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pak et al. (US 4851221 PTO-892).

Pak et al. discloses that administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia and hypertension (see col.1 lines 49-50, 63-68; col.3 lines 42-43, 46; col.8 line 35-36; col.9 line 50-67; claim 20). The calcium citrate composition of Pak et al. is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide (see abstract, and claim 18-20). Pak's disclosure of administering the same amount of calcium citrate composition to a postmenopausal woman would inherently increase HDL level in plasma of a postmenopausal woman, as claimed herein since the host, the amount, and the pharmaceutical active are the same in both Pak and the instant application. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001), regarding inherency as it related to the claimed invention herein.

Thus, the disclosure of Pak et al. anticipates claims 1-4, 6-9, 11-15, and 17-22.

Applicant's arguments filed on December 16, 2003 with respect to the rejection of claims 1-9, 11-15, and 17-21 made under 35 U.S.C. 102(b) as being anticipated by Ruml et al. of record in the previous Office Action September 23, 2003 have been considered but are moot in view of the new ground(s) of rejection above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', with a long, sweeping horizontal line extending to the right.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
March 10, 2004